ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD-FRL-XXX]

RIN-2060-AE83

National Emission Standards for Hazardous Air Pollutants Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of public hearing.

SUMMARY: The proposed standard would reduce air emissions of hazardous air pollutants (HAP) from existing and new facilities that manufacture pharmaceutical products. The agency intends that this proposed rule will have a common technology basis with a rule yet to be issued by EPA's Office of Water (OW); this will allow coordinated and cost effective compliance planning by the industry. In addition to soliciting comments on various aspects of the proposed rule, this document also solicits comments on possible approaches for the OW rule.

The major HAP emitted by facilities covered by this proposed rule include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a human carcinogen and the other pollutants can cause noncancer health effects in humans. The proposed rule is estimated to reduce HAP emissions from existing facilities by 22,000 megagrams per year (Mg/yr). It also reduces volatile organic compound (VOC) emissions.

DATES: Comments. Comments must be received on or before [insert date 60 days after publication in the Federal Register].

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by [insert date 3 weeks after publication in the Federal Register], a public hearing will be held on [insert date 30 days from date of publication] beginning at 10 a.m. Persons interested in attending the hearing should call Ms. Marguerite Thweatt at (919) 541-5673 to verify that a hearing will be held.

Request to Speak at Hearing. Persons wishing to present oral testimony must contact EPA by [insert date 3 weeks after publication] by contacting Ms. Marguerite Thweatt.

ADDRESSES: Comments. Comments should be submitted (in duplicate, if possible) to: Air Docket Section (LE-131), Attention: Docket No. A-96-03, U. S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The EPA requests that separate copies also be sent to the appropriate contact persons listed below. The public hearing, if required, will be held at the EPA's Office of Administration Auditorium, Research Triangle Park, North Carolina.

Supplementary Information. The information contained in this notice is also on the Technology Transfer Network (TTN). The TTN, EPA's electronic bulletin board, provides information and technology exchange in various areas of air

pollution control. The service is free, except for the cost of a telephone call. Dial (919) 541-5472 for up to a 14,400 bps modem transfer. In addition, the basis and purpose document (BPD), containing much of the rationale for these proposed standards, is also available on the TTN. The supplementary information document (SID) for the proposed standard, which contains a compilation of technical memoranda, may be obtained from the docket (entry #II-B-1).

Docket. Docket No. A-96-03, containing supporting information used in developing the proposed standards, is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at EPA's Air Docket Section, Waterside Mall, Room 1500, 1st Floor, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

For information concerning the MACT standard, contact Mr. Randy McDonald at (919) 541-5402, Organic Chemicals Group, Emission Standards Division (MD-13), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For further information concerning the effluent limitation guidelines pretreatment standards and new source performance standards, contact Dr. Frank H. Hund, at (202) 260-7786, Engineering and Analysis Division (4303), U. S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

Regulated entities. Entities potentially regulated are those which produce pharmaceutical products and

intermediates and are located at facilities that are major sources as defined in section 112 of the CAA. Regulated categories and entities include:

Category	Regulated entities
Industry	· Producers of material described by the SIC code 283
	· Producers of fermentation, biological or natural extraction, chemical synthesis, and formulation products regulated by the Food and Drug Administration
	· Producers of components (excluding excipients) of a pharmaceutical formulations or intermediates used in the production of a pharmaceutical product

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should carefully examine the applicability criteria in §63.1250 of the rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding "FOR FURTHER INFORMATION CONTACT" section.

The information presented in this preamble is organized as follows:

H. Miscellaneous

I. List of Source Categories

Section 112 of the amended Act requires that EPA evaluate and control emissions of HAP. The control of HAP is achieved through promulgation of emission standards under sections 112(d) and 112(f) and work practice and equipment standards under section 112(h) for categories of sources that emit HAP. On July 16, 1992, EPA published an initial list of major and area source categories to be regulated (57 FR 31576). Included on that list were major sources emitting HAP from pharmaceuticals production.

Production methods used in the manufacture of pharmaceutical products include both batch and continuous operations, although batch operations make up a majority of the processes. The sizes of the facilities range from those that make one product at the rate of several hundred kilograms per year (kg/yr) to those that produce numerous intermediates and final products on the scale of thousands of kilograms (megagrams [Mg]) per year. Air emissions of HAP compounds originate from breathing and withdrawal losses from storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization of HAP from wastewater streams. Pollutants (HAP) emitted from the production processes include a range of compounds, including VOC. Among the most prevalent are methylene chloride and methanol, which account for nearly 70 percent of all HAP

emissions from this industry. Detailed information describing manufacturing processes and emissions can be found in the Basis and Purpose Document.

As of 1992, over 80 U.S. companies at 270 facilities were producing pharmaceutical products. Manufacturing operations covered by this NESHAP include chemical synthesis, formulation, fermentation, and extraction processes and are generally classified under standard industrial classification 283. An estimated 101 facilities are considered to be major sources according to the CAA criterion of having the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP, based on 1992 emissions data. The proposed standard would apply to all major sources that produce pharmaceuticals. Area sources would not be subject to this standard.

II. Background

A. Summary of Considerations Made in Developing This Rule

This regulation reduces emissions of many of the HAP listed in section 112(b)(1) of the CAAA. The alternatives considered in the development of this regulation, including those alternatives selected as standards for new and existing sources, are based on process and emissions data received from the existing facilities known by the EPA to be in operation.

Regulatory alternatives more stringent than the MACT floor (minimum control level) were selected when they were

judged to be reasonable, considering cost, nonair impacts, and energy requirements.

The proposed standards give existing affected sources 3 years from the date of promulgation to comply. This is the maximum amount of time allowed by the Act. New affected sources are required to comply with the standard upon startup.

Included in the proposed rule are methods for determining initial compliance as well as monitoring, recordkeeping and reporting requirements. All of these components are necessary to ensure that affected sources will comply with the standards both initially and over time. However, the EPA has made every effort to simplify the requirements in the rule. The EPA has also attempted to maintain consistency with existing regulations by either incorporating text from existing regulations or referencing the applicable sections.

In addition, this rule contains an important and innovative pollution prevention alternative for the pharmaceutical industry that provides an option to reduce solvent consumption in lieu of installing end-of-pipe controls. The EPA has developed a regulation that provides a pollution prevention compliance alternative to the traditional control requirements, and the EPA encourages the pharmaceutical industry to meet the CAA requirements through its use. This alternative demonstrates EPA’s commitment to developing regulations that are cost effective and flexible,

and that reduce monitoring, recordkeeping, and reporting burdens.

Representatives from other interested EPA offices and programs, including State and Regional environmental agency personnel, and representatives from industry participated in the regulatory development process as MACT partnership members. For example, Region II, acting as the lead, worked closely with the States of New York and New Jersey as well as the pharmaceutical industry in developing the pollution prevention alternative. The partnership members were given opportunities to review and comment on the regulation prior to proposal. Several issues presented in the solicitation of comments section reflect these comments. Industry, regulatory authorities, and environmental groups will have another opportunity to comment on the proposed standards and provide additional information during the public comment period.

B. Regulatory Background

The proposed rule implements section 112(d) of the Clean Air Act (CAA) amendments of 1990, which require the Administrator to regulate emissions of HAP listed in section 112(b) of the CAA. The intent of this rule is to protect the public health by requiring new and existing major sources to reduce generation of emissions by using pollution prevention strategies or to control emissions to the level achievable by the maximum achievable control technology (MACT), taking into consideration the cost of

achieving such emission reductions, any nonair quality and other air quality related health and environmental impacts, and energy requirements.

In 1978, EPA published a control techniques document entitled "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029. The control technique guidelines document (CTG) contains a presumptive norm for reasonably available control technology (RACT) for the manufacturing operations covered under SIC Codes 2833 and 2834. This proposed rule does not affect the presumptive RACT guidelines, although a portion of emissions sources are covered by both the proposed regulation and the CTG document.

In 1994, EPA promulgated National Emission Standards for Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks. Pharmaceutical processes, defined as processes that synthesize pharmaceutical intermediates or final products using carbon tetrachloride or methylene chloride as a reactant or process solvent, are subject to this rule. The EPA is proposing today to require control of leaking components that are currently not subject to the Negotiated Regulation for Equipment Leaks, but that contain HAP and are associated with processes in this source category.

III. Authority for National Emission Standards for Hazardous Air Pollutants (NESHAP) Decision Process

A. Source of Authority for NESHAP Development

Section 112 of the Clean Air Act gives the Environmental Protection Agency the authority to establish national standards to reduce air emissions from sources that emit one or more HAP. Section 112(b) contains a list of HAP to be regulated by NESHAP. Section 112(c) directs the Agency to use this pollutant list to develop and publish a list of source categories for which NESHAP will be developed; this list was published in the Federal Register on July 16, 1992 (57 FR 31576). The Agency must list all known categories and subcategories of "major sources" that emit one or more of the listed HAP. A major source is defined in section 112(a) as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit in the aggregate, considering controls, 10 tons per year or more of any one HAP or 25 tons per year or more of any combination of HAP.

B. Criteria for Development of NESHAP

The NESHAP are to be developed to control HAP emissions from both new and existing sources according to the statutory directives set out in section 112(d) of the Act. The statute requires the standards to reflect the maximum degree of reduction in emissions of HAP that is achievable for new or existing sources. This control level is referred to as the "maximum achievable control technology" (MACT). The selection of MACT must reflect consideration of the cost of achieving the emission reduction, any nonair quality

health and environmental impacts, and energy requirements for control levels more stringent than the floor (described below).

The MACT floor is the least stringent level for MACT standards. For new sources, the standards for a source category or subcategory "shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator" [section 112(d)(3)]. Existing source standards should be no less stringent than the average emission limitation achieved by the best performing 12 percent of the existing sources for categories and subcategories with 30 or more sources or the average emission limitation achieved by the best performing 5 sources for categories or subcategories with fewer than 30 sources [section 112(d)(3)]. The determination of the MACT floor for existing sources under today's rule is that the average emission limitation achieved by the best performing sources is based on a measure of central tendency, such as the arithmetic mean, median, or mode. The determination of percentage reduction in the production-indexed consumption factors used in the pollution prevention alternative is based on the criteria that the alternative must achieve emissions reductions equivalent to what would have been achieved by complying with the MACT.

IV. Summary of Proposed Standards

A. Source Categories to be Regulated

The proposed standards would regulate HAP emissions from pharmaceutical production facilities that are determined to be major sources. The standards would apply to existing sources as well as new sources.

B. Pollutants to be Regulated and Associated Environmental and Health Benefits

Pharmaceutical production facilities emit an estimated 34,000 Mg/yr of organic and inorganic HAP's. Organic HAP's include methylene chloride, methanol, toluene, dimethylformamide, and hexane as well as other HAP's. Hydrogen chloride is an inorganic HAP emitted by this industry. The proposed rule would reduce HAP emissions from pharmaceutical facilities by 65 percent. Some of these pollutants are considered to be carcinogenic, and all can cause toxic health effects following exposure, including nausea, headaches, and possible reproductive effects. The EPA does recognize that the degree of adverse effects to human health can range from mild to severe. The extent and degree to which the human health effects may be experienced is dependent upon (1) the ambient concentration observed in the area (e.g., as influenced by emission rates, meteorological conditions, and terrain), (2) the frequency of and duration of exposures, (3) characteristics of exposed individuals (e.g., genetics, age, pre-existing health conditions, and lifestyle) which vary significantly with the population, and (4) pollutant specific characteristics

(toxicity, half-life in the environment, bioaccumulation, and persistence).

Most of the organic HAP's emitted from this industry are classified as VOC. The proposed emission controls for HAP's will reduce non-HAP VOC emissions as well. Emissions of VOC have been associated with a variety of health and welfare impacts. Volatile organic compound emissions, together with nitrogen oxides, are precursors to the formation of tropospheric ozone. Exposure to ambient ozone is responsible for a series of public health impacts, such as alterations in lung capacity; eye, nose, and throat irritation; nausea; and aggravation of existing respiratory disease. Among the welfare impacts from exposure to ambient ozone include damage to selected commercial timber species and economic losses for commercially valuable crops such as soybeans and cotton.

Hydrogen chloride is listed under section 112(r) of the CAA. The intent of section 112(r), Prevention of Accidental Releases, is to focus on chemicals that pose a significant hazard to the community should an accident occur, to prevent their accidental release, and to minimize consequences should a release occur. Hydrogen chloride, along with the other substances listed under section 112(r)(3), is listed because it is known to cause, or may be reasonably anticipated to cause death, injury, or serious adverse effects to human health or the environment (see 59 FR 4478, January 31, 1994). Sources that handle hydrogen chloride in

greater quantities than the established threshold quantity under section 112(r)(5) will be subject to the risk management program requirements under section 112(r)(7) (see 58 FR 54190, October 20, 1993).

In essence, the MACT standards mandated by the CAA will ensure that all major sources of air toxic emissions achieve the level of control already being achieved by the better controlled and lower emitting sources in each category. This approach provides assurance to citizens that each major source of toxic air pollution will be required to effectively control its emissions. In addition, the emission reductions achieved by these proposed standards, when combined with the reductions achieved by other MACT standards, will contribute to achieving the primary goal of the CAA, which is to “protect and enhance the quality of the Nations's air resources so as to promote the public health and welfare and the productive capacity of its population” (the CAA, section 101(b)(1)).

C. Affected Sources

Emission points identified from pharmaceuticals production include process vents, equipment leaks, storage tanks, wastewater collection and treatment systems, and heat exchange systems.

The affected source for the purpose of this regulation is the facility-wide collection of process vents, storage tanks, wastewater and associated treatment residuals, heat exchange systems, cooling towers, and equipment components

that are associated with pharmaceutical manufacturing operations. Based on this definition of affected source, new sources are created by reconstructing existing sources or constructing new "greenfield" facilities. Also, if an additional pharmaceutical manufacturing process unit(s) is added to a plant site that is a major source, the addition will be subject to the requirements for a new source provided that the addition meets the definition of construction in § 63.2 of subpart A (General Provisions); the new unit has the potential to emit 10 tons per year or more of any one HAP or 25 tons per year or more of any combination of HAP; and the process unit(s) is dedicated.

D. Format of the Standards

The standards for process vents are presented in a combination of percent reduction and mass limit format. Facilities will have the option of using any control technology, as long as the HAP reductions or mass limitations are achieved. The format of the standards for storage tanks are a combination of equipment standard and performance standard--tanks which require control are required to be fitted with floating roofs or with add-on devices meeting a percent removal requirement. The standards for wastewater emission sources offer two alternative formats for achieving compliance, a percent removal, or the use of reference control technologies. Equipment leak standards are in the form of equipment/work practice standards. Facilities would be required to

implement the program specified in the proposed regulation to achieve compliance with the standard.

An alternative pollution prevention standard is also being proposed. This standard can be met in lieu of meeting separate standards for the four emission source types associated with each pharmaceutical production process. The format for this alternative standard is in a kg HAP consumption reduction per kg product format.

E. Basis and Level of Proposed Standards

Detailed information describing the approach used to determine MACT floors and regulatory alternatives for the pharmaceuticals production source category can be found in the basis and purpose document.

The proposed standards for existing and new affected sources are summarized in Table 1. The MACT standard for

TABLE 1. PROPOSED STANDARDS FOR NEW AND EXISTING SOURCES

Emission source	New or existing?	Applicability		Requirement	
		Applicability level	Cutoff	Control efficiency	Emission limit
Process vent	New	Processes	≥400 lb/yr uncontrolled	98%	
	Existing	Processes	≥2,000 lb/yr controlled	93%; 98% for individual vents meeting cutoff based on flow and emissions	2,000 lb/yr
Storage tanks	New and existing	≥10,000 gal and <20,000 gal	≥1.9 psia vapor pressure of liquid stored	90%	
		≥20,000 gal	≥1.9 psia vapor pressure of liquid stored	95%	
Wastewater	New and existing	>1 Mg/yr total HAP load from all POD within a process or any single POD	≥1,300 ppm at POD of Table 2 HAP	99% reduction of Table 2 HAP	
			≥5,200 ppmw at POD of total HAP load	99% reduction of Table 2 HAP 90% reduction of Table 3 HAP 95% reduction of total HAP using biotreatment	
		>1 Mg/yr total HAP load from facility	≥10,000 ppmw at POD of total HAP load	99% reduction of Table 2 HAP 90% reduction of Table 3 HAP 95% reduction of total HAP using biotreatment	
	New	>1 Mg/yr total HAP load from all POD within a process or any single POD	≥110,000 ppmw at POD of Table 3 HAP	99% reduction of Table 3 HAP	
Equipment leaks	New and existing	All components in HAP service excluding components covered by subpart H		LDAR program	

most existing process vents was set at the floor level of control. The MACT floor was determined from the 12 facilities that represented the best performing 12 percent of the existing 101 major sources. The floor was calculated to be 93 percent control facility-wide. The proposed standards would require existing sources to reduce emissions from the sum of all vents within a process to 900 kg/yr (2,000 pounds per year [lb/yr]), considering control, or meet an overall process control level of 93 percent. Both calculations meet the requirements of the floor as determined on a facility wide basis. Additionally, a regulatory alternative beyond the floor was developed that requires 98 percent control of some large vents. An applicability cutoff was developed for this alternative based on a linear equation relating vent flowrate and HAP load. The cost of this alternative above the floor is $1,000/Mg and was judged to be reasonable. Process vents meeting the annual emissions and flowrate criteria are required to achieve 98 percent control, independent of the overall 93 percent requirement.

The MACT standard for process vents at new sources was set at the floor level of control. The MACT floor was determined from the best controlled similar source and is based on the most stringent control level achieved for both chemical synthesis and formulation type processes. The proposed standards for new sources would require 98 percent

control of process vents with uncontrolled emissions greater than 180 kg/yr (400 lb/yr).

The MACT floor for small, medium, and large storage tanks is 90 percent control for tanks storing liquids with total HAP vapor pressure greater than or equal to 1.9 psia at existing sources. The floor was determined from the twelve facilities that had the highest control level for storage tanks. The EPA evaluated the impacts of a regulatory alternative beyond the floor that would require 95 percent control of tanks greater than or equal to 20,000 gallons. Floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than add-on control; and it can be applied to 20,000 gallon tanks. Therefore, there is no additional cost for the regulatory alternative above the floor. The MACT for new sources is set at the same level as the MACT for existing sources because it has been determined that no facility is controlling tanks beyond the level required by the regulatory alternative for existing sources; therefore MACT would be no less stringent than the floor. The proposed standards would require existing and new sources to control storage tanks having volumes greater than or equal to 38 cubic meters (m^3) (10,000 gallons), and storing material with a vapor pressure of greater than or equal to 13.1 kPa (1.9 psi). The proposed standards require that tanks with capacities greater than or equal to 38 m^3 and less than 75 m^3 be controlled to a level of 90 percent

and tanks greater than or equal to 75 m^3 be controlled to 95 percent. One of the following control systems can be applied to meet these requirements:

1. An internal floating roof with specified seals and fittings;

2. An external floating roof with specified seals and fittings;

3. An external floating roof converted to an internal floating roof with specified seals and fittings; or

4. A closed vent system with the appropriate 90 or 95 percent efficient control device.

The MACT floor for wastewater at existing sources was determined to be 54 percent control of HAP from the total wastewater streams at the top twelve facilities. The EPA calculated HAP concentration cutoffs for wastewater streams, cutoffs above which steam stripping of wastewater streams would result in a level of control as stringent as the floor. This approach is similar to the HON and allows for the control of those wastewater streams containing the most significant amount of HAP. The cutoffs represent the MACT floor level of control. The proposed standards would require existing sources to control wastewater with the following characteristics at the point of determination (POD):

1. Streams having partially soluble HAP compound concentrations of 1,300 ppmw or greater and a total yearly

process HAP load of 1 Mg/yr or greater or any single POD load of 1 Mg/yr or greater;

2. Streams having a combined total HAP concentration of 5,200 ppmw or greater and a total yearly process HAP load of 1 Mg/yr or greater or any single POD load of 1 Mg/yr or greater; or

3. Streams having a total HAP concentration of 10,000 ppmw with a total facility HAP load of 1 Mg/yr or greater.

The proposed standards require that the control of wastewater emissions be accomplished in one of the following manners:

1. Using a design biotreatment system for soluble HAP;

2. Demonstrating removals achieving 99 percent by weight of partially soluble compounds, and 90 percent by weight of soluble compounds, from treatment systems; or

3. Demonstrating a removal of 95 percent by weight of total organic HAP from treatment systems.

For new sources, the MACT floor for wastewater is based on a facility that currently incinerates a significant percentage of wastewater containing HAP's in an incinerator combusting a mixture of wastes. The proposed standards would require the same applicability and control requirements described above for existing sources plus require an increased removal of solubles (from 90 to 99 percent) for streams having a soluble HAP concentration

of 110,000 ppmw at any of the load criteria (1 Mg/yr total HAP from the process, POD, or facility).

The MACT floor for equipment leaks was found to be negligible for new and existing sources. The regulatory alternative above the floor is the implementation of a leak detection and repair program, patterned after 40 CFR part 63 subpart H. The cost of the regulatory alternative was estimated to be $1,000/Mg and was judged to be reasonable. The proposed standards would require that new and existing sources implement a leak detection and repair (LDAR) program that is modified from the program specified in the Negotiated Regulation for Equipment Leaks (40 CFR part 63, subpart H) to apply specifically to the pharmaceutical industry. The LDAR program specified under subpart H requires specific equipment modifications and work practices that reduce emissions from equipment leaks. Modifications to this program for this rule include the lessening of the monitoring frequency for pumps from monthly to quarterly monitoring (based on the specific data from pharmaceutical manufacturing operations) and the treatment of emissions from receivers and surge control vessels in the process vent provisions. In response to comments received from industry during the standard development process, EPA will consider consolidating the equipment leaks program specified in this subpart (appendix GGGA) with the part of the 40 CFR part 63 subpart H LDAR program that applies to pharmaceutical facilities after promulgation of subpart GGG. The EPA is

currently in the process of separately proposing clarifying changes to certain provisions of 40 CFR part 63 subpart H, among them, provisions relating to the monitoring requirements for unsafe and difficult to monitor components. Lastly, based on current industry comments that suggest minimal use of a Quality Improvement Plan (QIP) at pharmaceutical plants, EPA is considering eliminating the requirement of implementing a QIP for the pharmaceutical rule in favor of allowing more frequent monitoring when nominal leakage rates are exceeded and is soliciting comments on whether the QIP should be included in the subpart GGG LDAR program.

1. Alternative Pollution Prevention Standard.

The proposed rule also includes a pollution prevention (P2) alternative standard that meets the requirement of the MACT floor and can be implemented in lieu of the requirements described above for existing sources. Two options included in the alternative standard are described in Table 2. The P2 options were developed to provide a way for facilities to comply with the MACT standard by reducing overall consumption of HAP in their processes. This alternative does not apply to HAP that are used as reactants. In the first option, which is applicable to existing processes, owners and operators can satisfy the MACT requirements for all emission source types associated with each process by demonstrating that the production-indexed consumption of HAP has decreased by 75 percent from

a baseline set no earlier than the 1987 calendar year. The production-indexed consumption factor is expressed as kg HAP consumed/kg product produced. The numerator in the kg/kg factor is the total consumption of material, which describes all the different areas where material can be consumed, either through losses to the environment, consumption in the process as a reactant, or otherwise destroyed. Consumption, rather than emissions, is tracked because it can be used as a true measure of pollution prevention; any decrease in consumption for the same unit of product generated must involve some type of increase in process efficiency, including reduction of waste, increased product yield, and in-process recycling. Because HAP are used generally as solvents in this industry, reductions in consumption can be generally associated with reductions in losses to air, water, or solid waste.

TABLE 2. ALTERNATIVE P2 STANDARD

Option	Description of P2 option
1	Demonstrate a 75% reduction in the kg consumption/kg production factor from a baseline year of 1987.
2	Demonstrate a 50% reduction in the kg/kg and additional reduction from add-on control equivalent to yield 75% overall reduction in kg/kg.

The second option also uses the production-indexed consumption factor and is also applied to existing processes. It encourages and allows owners and operators to supplement reductions achieved with P2 with add-on controls. The EPA believes that such an option will provide greater

flexibility and cost efficiency to the operators who already may have some add-on controls. Owners and operators must demonstrate reductions in the kg/kg factor of 50 percent via P2 measures and the remaining 25 percent by add-on controls. A total reduction of 75 percent will be required under both P2 options.

F. Compliance and Performance Test Provisions

1. Proposed Standards

a. Process Vents. To determine compliance with the percent reduction requirement for pharmaceutical process vents, uncontrolled and controlled emissions from all process vents within the process shall be quantified to demonstrate the appropriate overall reduction requirements (93 percent or 98 percent). For process vents controlled by devices handling less than 10 tons per year, the owner or operator can either test or use calculational methodologies to determine the uncontrolled and controlled emission rates from individual process vents. For process vents controlled by devices handling more than 10 tons per year, tests are required to determine the reduction efficiency of each device. Performance test provisions have been structured to account for the worst case emissions for devices controlling streams with batch characteristics. Control devices that have previously been tested under conditions required by this standard and condensers are exempt from performance testing.

b. Storage Tanks and Wastewater. For demonstrating compliance with various requirements, the proposed rule allows the owners or operators to either conduct performance tests or to document compliance using engineering calculations. Appropriate compliance and monitoring provisions are specified in the regulation.

c. Equipment Leaks. To determine compliance with the standard for equipment leaks, facilities will have to demonstrate that a LDAR program meeting the requirements of the LDAR program specified in the rule is in use.

2. Pollution Prevention Alternative Standards

Initial demonstration of compliance with the P2 alternative standards would be accomplished by documenting yearly quantities of HAP raw materials and products using available records, including standard purchasing and accounting records, and calculating the kg/kg values. Procedures are also specified to demonstrate that the required reductions are achieved by the control devices used to meet option 2.

G. Monitoring Requirements

1. Actual Standards

Monitoring is required by the proposed standards to determine whether a source is in compliance on an ongoing basis. This monitoring is done either by continuously measuring emission reductions directly or by continuously measuring a site-specific operating parameter, the value of which is established by the owner or operator during the

initial compliance determination. The operating parameter value is defined as the minimum or maximum value established for a control device or process parameter that, if achieved on a daily average by itself or in combination with one or more other operating parameter values, determines that an owner or operator is complying with the applicable emission standards. These parameters are required to be monitored at 15-minute intervals throughout the operation of the control device. For devices controlling streams totaling less than 1 ton/yr, only a site-specific periodic verification that the devices are operating as designed is required to demonstrate continuous compliance. Owners and operators must determine the most appropriate method of verification and propose this method to the Agency for approval in the precompliance report, which is due 1 year prior to the compliance date of the standard.

2. Alternative Standard

Owners and operators electing to use the P2 alternative can demonstrate ongoing compliance by calculating a monthly rolling average of the kg HAP/kg factor for each applicable process or portions of the process. In addition, owners and operator electing to use P2 Option 2 would have to monitor the emission reduction obtained through the use of traditional controls using the methods described above.

H. Reporting and Recordkeeping Requirements

The owner or operator of any pharmaceutical source subject to these standards would be required to fulfill all

reporting requirements outlined in the General Provisions to 40 CFR part 63. A table included in the proposed rule designates which sections of subpart A apply to the proposed rule. Specific recordkeeping and reporting requirements for each type of emission point are also included in the proposed rule.

V. Summary of Environmental, Energy, Cost, and Economic Impacts

A. Facilities Affected by These NESHAP

These NESHAP would affect pharmaceutical production facilities that are major sources in themselves, or constitute a portion of a major source. There are 270 existing facilities manufacturing pharmaceuticals, 101 of which were assumed to be major sources for the purpose of developing these standards and calculating impacts. The expected rate of growth for the pharmaceutical industry is expected to be 2.4 percent per year through 1998.

B. Air Impacts

The proposed standards would reduce HAP emissions from existing sources by 22,000 (Mg/yr) (24,000 tons per year [tons/yr]) from the baseline level, a reduction of 65 percent from baseline, and 75 percent from uncontrolled. These reduction would also occur if facilities elect to implement the alternative pollution prevention standard. The proposed standard would also reduce VOC emissions.

C. Water and Solid Waste Impacts

Much of the steam stripping operations will result in recoverable material. However, the new source requirement for very rich soluble HAP-containing wastewater is expected to generate solid waste. An average of 900 tons per year per facility was estimated to determine impacts.

D. Energy Impacts

The proposed standards for the pharmaceuticals source category would require an additional energy usage of $2,400 \times 10^9$ British thermal units per year (Btu/yr).

E. Cost Impacts

The emission reductions that would be required by this regulation could be met using one or more of several different techniques. To determine costs, certain control scenarios were assumed. The scenarios used in costing were judged to be the most feasible scenarios possible for meeting the requirements of the proposed standards from a technical and cost standpoint. The total control cost includes the capital cost to install the control device, the costs involved in operating the control device, and costs associated with monitoring the device to ensure compliance. Monitoring costs include the cost to purchase and operate monitoring devices, as well as reporting and recordkeeping costs required to demonstrate compliance. Nationwide, the total annual cost of this standard to the industry for existing and new sources is approximately $62 million and $11 million respectively. The EPA believes that monitoring,

reporting, and recordkeeping costs will be substantially reduced for the facilities opting to comply via the P2 option. Additionally, EPA also believes that overall control costs will also be substantially reduced as a result of compliance with the P2 option.

F. Economic Impacts

The economic impact analysis of this standard shows that the estimated price increase from compliance with the recommended standard for process vents, storage tanks, and wastewater is 1.1 percent. Estimated reduction in market output is 1.9 percent.

No plant closures are expected from compliance with this set of alternatives. For more information, consult the economic impact report entitled "Economic Analysis of Air Pollution Regulation Regulations: Pharmaceutical Industry, August 1996."

VI. Emissions Averaging

Emissions averaging is being considered as part of this rule. The rule includes provisions that permit emissions averaging within existing process vent and storage tank planks. The industry is interested in emissions averaging for only these two emission point types. The provisions consist of a streamlined version of the Hazardous Organic NESHAP (HON) emissions averaging provisions (40 CFR part 63 subpart G) modified specifically for the pharmaceutical industry. However, the constraints are essentially the same as those contained in the HON.

VII. Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Water Act

The Clean Water Act (CWA) and a recent settlement agreement (see 59 FR 25869) require EPA to develop effluent limitations guidelines and standards regulations for certain industrial categories. The Pharmaceutical Manufacturing Industry is one of the categories required to be regulated by this settlement agreement. The EPA's most recent regulatory proposal for the pharmaceutical industry was on May 2, 1995 (60 FR 21592.)

In the May 2, 1995 proposal, EPA proposed best available technology (BAT) economically achievable and new source performance standards (NSPS) regulations for 53 volatile and semivolatile organic pollutants of which 17 are HAP. The Agency also proposed PSES and PSNS for 45 volatile organic pollutants of which 16 are HAP. [Air emissions of HAP by major sources will be controlled by this MACT rule provided that the wastewater streams containing the HAP meet concentration criteria for soluble and partially soluble HAP in today's proposal.]

The EPA identified the following industry subcategories in the proposed effluent guidelines: fermentation (A), biological and natural extraction (B), chemical synthesis (C) and formulation (D).

The proposed BAT end-of-pipe limitations would control the discharge of 17 HAP and 36 non-HAP at both A and C and B and D manufacturing facilities. The technology basis for

the BAT limitations for A and C subcategory facilities was in-plant steam stripping followed by advanced biological treatment while the technology basis of the BAT limitations for B and D subcategory facilities was advanced biological treatment. Since these proposed limitations are set at the end-of-pipe, they would not prevent air emissions of these pollutants prior to discharge.

Also proposed in the May 2, 1995 notice (see coproposal A) were PSES for 8 HAP and 4 non-HAP set in-plant at a point roughly equivalent to the MACT standards point of determination while PSES for 8 other HAP and 25 non-HAP were proposed at the end-of-pipe discharge point. The technology basis for the HAP and non-HAP pollutants alike was steam stripping. Under coproposal B, only in-plant PSES for the eight HAP would be established. The Agency decided to establish an in-plant monitoring point for 12 highly volatile pollutants (including the 8 HAP) because measuring compliance at the end-of-pipe monitoring point was not considered practical for these pollutants due to the high potential for air stripping associated with them and commingling with other process wastewater not containing any of the 12 pollutants. As is the case with the BAT end-of-pipe limitations, the end-of-pipe proposed PSES would not prevent air emissions of HAP at facilities prior to the discharge point to the municipal sewer systems.

The MACT standards being proposed today will control HAP emissions (if promulgated) at major source

pharmaceutical plants with steam stripping as the reference control technology. The EPA is considering revising the BAT limitations for subcategories A and C based on only advanced biological treatment performance data. This would in effect shift control of HAP air emissions and wastewater pollutant discharges of the HAP to the MACT standards. With regard to control of non-HAP at major sources, the Agency believes that the significant reductions in HAP emissions required by the proposed MACT standards will also result in incidental reductions in non-HAP air emissions because many non-HAP are found in the same wastewater streams as the HAP, and thus will be steam stripped along with the HAP. While control of air emissions of HAP and non-HAP VOC's will be addressed to some extent under the CAA, additional control of water discharges of the VOC's from direct dischargers needs to be addressed under the Clean Water Act using as a basis the BAT limitations and NSPS proposed on May 2, 1995.

The MACT standards being proposed today would apply to select streams at 60, out of a possible 259, pharmaceutical indirect dischargers deemed to be major sources of air emissions. Only those streams which meet the flow and concentration cutoffs established for HAP would require control. Assuming that EPA's pass-through analysis does not change and coproposal A is chosen, EPA estimates that today's proposed MACT rule would reduce the load of VOC's to POTW's from pharmaceutical manufacturing plants by approximately 48 percent. Part or all of the remainder of the

pollutant loadings to POTW's may need to be controlled by additional pretreatment requirements. The Agency is considering three options for setting pretreatment standards (PSES and PSNS) to address HAP and non-HAP wastewater pollutant discharges not controlled by today's proposed MACT standard.

Under the first option (which has been suggested by commenters), compliance with today's MACT standards would constitute compliance with final PSES and PSNS for all manufacturing subcategories. However, since compliance with the MACT regulation requires only one demonstration by the facility, EPA is considering some form of regular monitoring to verify compliance with wastewater discharge standards. Facilities could either monitor for individual HAP or non-HAP on a regular basis or for some indicator pollutant parameter whose regulatory compliance level would be established at the same time that MACT rule compliance demonstration is performed. This option would result in control of about 48 percent of the VOC pollutant load that is currently being discharged to POTW's by pharmaceutical facilities.

Under the second option, and in addition to the MACT regulations on selected streams at 60 indirect dischargers, EPA would establish pretreatment standards for the streams and pollutants not controlled by the MACT regulations. The level of control dictated by these additional standards would be the same level as that of the MACT standards

(90 percent reduction for soluble organics and 99 percent for partially soluble organics). The pretreatment standards could either be in the form of percent reduction requirements for individual pollutants or single number standards resulting from the application of the MACT percent reduction requirements. The EPA estimates that this option would reduce the discharge of pollutants to POTW's by an additional 45 percent over the first option.

The third option would involve promulgating the coproposal A pretreatment standards for all indirect dischargers at the end-of-pipe regulatory point. These pretreatment standards would apply to all streams at facilities designated as major sources regardless of whether the streams were within the concentration cutoffs for HAP and would be established for all pollutants which pass-through. The level of control dictated by these standards would be the coproposal A level with the exception that standards for 12 pollutants which were established in-plant will now be set at the end-of-pipe and adjusted downward to account for dilution due to mixing with other waste streams. Other changes in parameters or limitations may result from the evaluation of comments and receipt of additional performance data. Using the proposed limitations, EPA estimates that this option would reduce the discharge of pollutants to POTW's by an additional 29 percent over the first option.

The EPA is considering revising its pass-through analysis for water soluble, biodegradable pollutants such as methanol, acetone, isopropanol and ethanol based on approaches suggested by commenters on the May 2, 1995 pharmaceutical proposal as well as the approaches used in the Pesticide Chemicals Manufacturing and Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) rulemakings. In general, pollutants are considered to pass-through POTW's if the average percent removal achieved by well operated POTW's is less than that achieved by the BAT model treatment systems. The EPA is considering specifically the methodology modifications employed in the evaluation for phenol, a biodegradable water soluble pollutant as discussed in the Pesticides and OCPSF rulemakings (see 59 FR 50638, 50664-65, September 28, 1993 and 58 FR 36872, 36885-86, July 9, 1993). Among the modifications suggested by the commenters were: (1) using only data from acclimated POTW systems to determine POTW removal; (2) finding no pass-through for pollutants if the differential between the model BAT percent removal and the POTW percent removal for a pollutant is less than 5 percent and; (3) utilizing a higher Henry's Law Constant cutoff when pass through is determined by the volatile override approach (pollutants which have a higher Henry's Law Constant value than the cutoff are presumed to pass-through using this methodology).

The Agency is reevaluating its proposed pass-through analysis because of the comments received concerning it and

to be more consistent with today's proposed MACT standards for soluble organic HAP which allows the biodegradation achieved by POTW's to be included in the compliance demonstration for these pollutants. Today's MACT standards require a demonstration of at least a 90 percent reduction in air emissions from wastewater of water soluble biodegradable HAP. As a result, a finding of pass-through may result in duplicative and somewhat inconsistent control (by water and air regulations) for some pollutants. The EPA solicits comments on possible revisions to its pass-through methodology as applied to water soluble, biodegradable pollutants.

The EPA is soliciting comments on approaches for revising the limitations for direct and indirect dischargers in the proposed effluent guidelines for the pharmaceutical industry (60 FR 21592, May 2, 1995). The intent of all of these approaches is to integrate the regulation of emissions into the air and waters of the United States. If EPA develops any additional data related to the possible revisions, those data will be made available to the public.

The EPA may proceed with final action on the effluent guidelines, taking into account comments and data received in response to this notice.

VIII. Solicitation of Comments

The Administrator welcomes comments from interested persons on any aspect of the proposed rule, and on any statement in the preamble or the referenced supporting

documents. The proposed rule was developed on the basis of information available. The Administrator is specifically requesting factual information that may support either the approach taken in the proposed standards or an alternate approach. In order to receive proper consideration, documentation or data should be provided. This section requests comments on specific issues identified during the development of the standard. Additionally, EPA is soliciting comments regarding the interaction of this standard with the Title V operating permits program.

The EPA is requesting comments and data on establishing the applicability of process vent control requirements on a process basis, as opposed to an equipment or facility basis. The basis and purpose document included in the administrative record outlines the rationale for establishing applicability on a process basis. Second, the EPA is soliciting general comments on the adequacy of emission estimation procedures to determine compliance for batch processes. Comments from State partnership members indicate that some batch operations, such as distillation, may contribute to considerably more emissions than would otherwise be predicted. In some cases, unless 100 percent capture is achieved by the condenser acting as a recovery device on boiling operations, there may be uncontrolled emissions that are not being estimated. The State partnership members recommend that facilities compare their HAP mass balance to estimated HAP losses. When large

discrepancies exist, the facility may need to monitor large process condensers. Third, the EPA is soliciting comments on the definition of a pharmaceutical product and isolated intermediate. In particular, whether Standard Industrial Classification code #283 and coverage by the Food and Drug Administration (FDA) rules are adequate to identify a pharmaceutical process covered by this regulation. The proposed rule considers isolated intermediates to be the same as pharmaceutical products in applicability determinations, e.g., the 2,000 lb/yr cutoff applies to isolated intermediates. The EPA is soliciting comments on the definition of isolated intermediates and the appropriateness of applying the cutoff to isolated intermediates. Fourth, EPA is soliciting comment on the adequacy and appropriateness of the new source MACT requirements for process vents. As set out in the basis and purpose document, EPA set the cutoff and level of control for the floor based on its analysis of the data showing that the characteristics of the emission streams are similar. The industry, however, believes that the basis of the cutoff is not representative of the industry as a whole. The EPA will consider other proposals for setting the cutoff at a less stringent level, taking into consideration statutory and regulatory requirements.

The EPA is soliciting comments on several aspects of performance testing and monitoring. The rule currently requires performance testing to document efficiencies for

control devices that are used to reduce uncontrolled emissions of 10 tons per year or more. The rule currently requires that the performance test be conducted under "worst-case" conditions and provides for three options -- absolute, representative, and hypothetical worst-case. The rule also allows for testing during normal operations. However, because of the noncontinuous, batch nature of processing in this industry, testing under normal conditions may not indicate control device performance under more challenging conditions. Therefore, the proposed rule requires that the test conditions be defined and operation be limited by those conditions that existed during testing. The rule requires that the test conditions be defined in the Precompliance report and characterized by the HAP composition and conditions of vent stream entering the control device. It is because of the batch nature of processing in this industry that the EPA has a higher level of confidence in a facility’s compliance with the standard if the performance of the control device has been tested under worst-case conditions. Therefore, testing under less rigorous, normal conditions limits the range of vent stream conditions for which initial compliance has been demonstrated. The EPA is soliciting comments on appropriate test conditions to be defined for different types of control devices, especially scrubbers and carbon adsorbers.

The proposed rule provides for parametric monitoring to comply with the standard and includes specific operating

parameters to be monitored. The EPA is soliciting comments on the use of alternative parameters without the requirement of prior notification in the Precompliance report. Parameters other than those specified in the rule that could be used to demonstrate compliance include: (1) for condensers, coolant temperature and flow (only with emissions testing), (2) for scrubbers, measurement of pressure drop or scrubber fluid composition, and (3) for carbon adsorbers, periodic vent testing and/or predetermined scheduled replacement. The EPA is soliciting comment on the adequacy of these parameters for demonstrating continuous compliance with the rule.

An issue raised by industry associated with parametric monitoring is related to the setting of a parameter based on an initial compliance determination at conditions which represent the upper limit (with regard to achievable control) of conditions that will be encountered during the course of operations. The concern is that the rule effectively requires a control level that is greater than the standard because the control devices will presumably achieve higher control on conditions that are below this upper limit, which may occur frequently in this industry because of the predominance of batch processes. The EPA has tried to resolve this issue by allowing owners and operators to set more than one parameter level for a given control device for processes or portions of processes not requiring control levels as high as the worst-case or upper limit.

These parametric levels are required to be defined in advance in the Notification of compliance report. If more than one level is set, owners and operators must make a determination of compliance with the standards based on what processes or emission characteristics are routed to the device at the time in which a monitoring reading is taken. Additionally, the determination of an exceedance is based on a maximum of 24 hours worth of data, or 96 15-minute readings, per process. Therefore, readings outside of acceptable ranges can be averaged in with readings that are within range and effectively normalized. The EPA believes that the approach taken offers the industry needed flexibility while preserving the assurance of continuous compliance.

Another issue raised by industry is related to predictability of operations. The industry believes that nondedicated, multiproduct facilities using control devices other than condensers (and, perhaps, combustion devices) for multiple vents may not be able to anticipate all possible operating scenarios for which a separate parametric level would need to be set. The industry has given the example of a scrubber that is used to control emissions from multiple processes. The parametric level that represents compliance with the applicable standard for each process may change depending on what is happening in each process and they argue it would be essentially impossible to predict the exact scrubber flow needed to achieve compliance at any

given time. The industry has requested that the standard provide that an excursion from a parametric level does not automatically constitute a violation of the rule, but instead triggers reporting requirements that initiate a permitting authority's review to decide whether the excursion resulted in a violation for this type situation. The EPA has generally taken the position that "after-the-fact" justification of excursions is not an appropriate compliance strategy. Based on currently available information, the EPA has not seen a need to change this position. The proposed rule allows the facility flexibility in establishing the parameter monitoring level based on tests, engineering assessments, and/or manufacturers recommendations if included in the Precompliance report and approved. The EPA believes it is necessary to know the HAP load going to the control device to be able to properly operate the device to meet the emission limit (the agency has concerns about the industry's stated inability to predict or know the HAP load at certain times). In cases where the owner cannot predict exactly what is going to the control device over time, the standard provides for doing testing under conditions worse than average to cover periods of uncertainty. In fact this is the reason for the focus on worst-case in the rule. The EPA is seeking comment on this part of the rule.

Related to testing and monitoring are management of change issues. The EPA is soliciting general comments on

the clarity of the rule as it applies to process changes. Management of change issues are also related to title V of the Clean Air Act.

Currently, the Notification of Compliance report is the compliance "blueprint" for implementation of the standard. All information regarding documentation of the facility's compliance status with regard to the standard should be included in this report. Process descriptions, emission estimates, control device performance documentation, and continuous compliance demonstration strategies, including monitoring, are to be presented in the report. This report could be incorporated by reference into the facility's title V permit. If a change occurred at the facility which required the submittal of additional information, or if the plant chose to revise procedures that had been previously documented in the notification, this information would be submitted in quarterly reports, thus ensuring that the notification and associated reports would always contain the most current compliance strategy for the facility. Only changes requiring site-specific approval, such as the use of a monitoring parameter that was not specifically identified in the standard, would trigger some significant review action under title V. This would allow the facility enough flexibility to change processes, operating, and compliance procedures as necessary without prior approval, if the changes were straightforward, and would assure that the compliance plan for the facility would always be current.

The EPA is also soliciting comments on the incorporation by reference of the Notification of Compliance report into the title V permit, and comments on the types of changes that should trigger review actions under title V.

IX. Administrative Requirements

A. Public Hearing

A public hearing will be held, if requested, to discuss the proposed standard in accordance with section 307(d)(5) of the Clean Air Act. Persons wishing to make oral presentation on the proposed standards for pharmaceutical production processes should contact EPA at the address given in the ADDRESSES section of this preamble. Oral presentations will be limited to 15 minutes each. Any member of the public may file a written statement before, during, or within 30 days after the hearing. Written statements should be addressed to the Air Docket Section address given in the ADDRESSES section of this preamble and should refer to Docket No. A-96-03.

A verbatim transcript of the hearing and written statements will be available for public inspection and copying during normal working hours at EPA's Air Docket Section in Washington, DC (see ADDRESSES section of this preamble).

B. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by EPA in

the development of this proposed rulemaking. The principal purposes of the docket are:

1. To allow interested parties to readily identify and locate documents so that they can intelligently and effectively participate in the rulemaking process; and

2. To serve as the record in case of judicial review (except for interagency review materials [section 307(d)(7)(A)]).

C. Executive Order 12866

Under Executive Order 12866, [58 FR 51735 (October 4, 1993)] the Agency must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

1. Have an annual effect of the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, the OMB has notified the EPA that it considers this a "significant regulatory action" within the meaning of the Executive Order. The EPA submitted this action to the OMB for review. Changes made in response to suggestions or recommendations from the OMB were documented and included in the public record.

D. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875, EPA has involved State governments in the development of this rule. These governments will be required to implement the rule. They will collect permit fees which will be used to offset the resource burden of implementing the rule. Representatives of six State governments are members of the MACT partnership. This partnership group was consulted throughout the development of this proposed regulation. Comments from the partnership members were carefully considered. In addition, all States are encouraged to comment on this proposed rule during the public comment period, and the EPA intends to fully consider these comments in the final rulemaking.

E. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1681.01), and a copy may be obtained from Sandy Farmer, Information Policy Branch, U. S. Environmental Protection Agency, 401 M Street SW. (2137), Washington, DC 20460, or by calling 202-260-2740. The public reporting burden for this collection of information is estimated to average 4,800 hours per respondent for the first year and 2,600 hours per respondent for each of the second and third years, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2137, U. S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) provides that, whenever an agency promulgates a final rule under 5 U.S.C.

§ 553, after being required to publish a general notice of proposed rulemaking, an agency must prepare a final regulatory flexibility analysis unless the head of the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), I certify that this rule will not have a significant impact on a substantial number of small entities.

The EPA analyzed the potential impact of the rule on small entities and determined that only 16 of 56 pharmaceutical producing firms are small entities -- not a substantial number of entities. Of these 16 firms, only four will experience an increase in costs as a result of the promulgation of today's rule that are greater than 1 percent of revenues. Therefore, the Agency did not prepare an initial regulatory flexibility analysis.

Although the statute does not require EPA to prepare an RFA because the Administrator has certified that the rule will not have a significant economic impact on a substantial number of small entities, EPA did undertake a limited assessment, to the extent it could, of possible outcomes and the economic effect of these on small pharmaceutical entities. The initial version of that evaluation is available in the administrative record for today's action.

G. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small

governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that the proposed standards do not include a Federal mandate that may result in estimated costs of, in the aggregate, $100 million or more to either State, local or Tribal governments, or to the private sector, nor do the standards significantly or uniquely impact small governments, because they contain no requirements that apply to such governments or impose obligations upon them. Therefore, the requirements of the Unfunded Mandates Act do not apply to this final rule.

H. Miscellaneous

In accordance with section 117 of the Act, publication of this proposal was preceded by consultation with appropriate advisory committees, independent experts, and Federal departments and agencies. The Administrator will welcome comments on all aspects of the proposed regulation, including health, economic and technical issues, and on the proposed test methods.

This regulation will be reviewed 8 years from the date of promulgation. This review will include an assessment of such factors as evaluation of the residual health and environmental risks, any overlap with other programs, the

existence of alternative methods, enforceability, improvements in emission control technology and health data, and the recordkeeping and reporting requirements.

LIST OF SUBJECTS IN 40 CFR PART 63

Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated:

Carol M. Browner,
Administrator